

AMENDMENT AND RESPONSE TO OFFICE ACTION

Serial Number: 09/657,404

Filing Date: 09/08/2000

Title: Improved Rate-Adaptive Therapy with Automatic Limiting of Maximum Pacing Rate

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Dkt: 279.279US1

REMARKS

Claims 1-25 are presently pending in the case. Claims 1-25 were rejected in the office action on various grounds. Applicant addresses below each of the grounds of rejection applied to the claims.

Rejections Under 35 U.S.C. § 112

Claims 1-25 were rejected in the Office Action under 35 U.S.C. 112, second paragraph, as being indefinite. Claims 1, 3, 5, 7, 10, 11, 13-15, 17, 19-21, and 24 have been amended herein in a manner which overcomes the rejections.

Rejections under 35 U.S.C. § 102(e)

Claims 1-25 were rejected under 35 U.S.C. 102(e) as being anticipated by Kay (U.S. Patent No. 6,411,850). The rejections are respectfully traversed in detail as follows.

Among other things, applicant is unable to find a teaching in the cited portions of Kay: a method for operating a rate-adaptive pacemaker in which a rate response curve is defined such that an exertion level corresponding to the patient's maximum exercise capacity would be mapped to a physiologically favorable maximum rate, MAR, the sensor indicated rate is limited to a specified maximum sensor indicated rate MSR that is independent from the MAR, and the MSR is increased after a specified time period during which the long-term maximum exertion level is updated, as recited by claim 1.

Applicant repeats the discussion of claim 1 in support of the patentability of claim 25.

Applicant is unable to find in the cited portions of Kay, among other things: a rate-adaptive pacemaker in which a rate response curve is defined such that an exertion level corresponding to the patient's maximum exercise capacity would be mapped to a physiologically favorable maximum rate, MAR, means for limiting the sensor indicated rate to a specified maximum sensor indicated rate MSR that is independent from the MAR, and means for increasing the MSR after a specified time period during which the long-term maximum exertion level is updated, as recited by claim 15.

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Reconsideration and withdrawal of the rejections of claims 1, 15, and 25 is respectfully requested. The recitations of dependent claims 2-14 (ultimately dependent on claim 1) and 16-24 (ultimately dependent on claim 15) are believed patentable for at least the reasons presented for their base independent claim, respectively, and are believed not to be taught or suggested by Kay. Reconsideration and withdrawal of the rejections of dependent claims 1-14 and 16-24 are thus also respectfully requested.

Applicant respectfully traverses the assertion made in the office action relating peak ventilation and the MAR. Applicant refers to at least the original specification, page 16, lines 3-6 for clarification of the MAR. Reconsideration and withdrawal of the assertion is respectfully requested.

Timely Traversal of Assertions of Things Known to One of Skill in the Art

Applicant generally traverses the assertion of things "known to one of skill in the art" as a form of Official Notice and requests a reference to support such assertions pursuant to MPEP 2144.03, or their withdrawal in the next official communication.

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CONCLUSION

Applicant believes the application is in condition for allowance and respectfully requests such action. Please charge any fees deemed necessary to Deposit Account 19-0743. The examiner is invited to telephone the below-signed attorney at 612-373-6912 to discuss any questions that may remain with respect to the present application.

Respectfully submitted,

Weimin Sun et al.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6912

Date Feb. 03, 2003 By T. E. B.
Timothy E. Bianchi
Reg. No. 39,610

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner of Patents, Washington, D.C. 20231 on February 3rd, 2003.

Name

GREG HANSON

Signature

Greg Hanson

RA



Docket No. 00279.279US1

Clean Version of the Amended Claims

**IMPROVED RATE-ADAPTIVE THERAPY WITH AUTOMATIC
LIMITING OF MAXIMUM PACING RATE**

Applicant: Weimin Sun et al.
Serial No.: 09/657,404

Please replace claims 1, 3, 5, 7, 10, 11, 13-15, 17, 19-21, and 24 with their corresponding claims, as amended, below:

A1
1. (Amended) A method for operating a rate-adaptive pacemaker wherein measured exertion levels in a patient are mapped to a sensor indicated rate by a rate response curve, comprising:

automatically determining the patient's maximum exercise capacity as defined by a long-term maximum exertion level by collecting maximum measured exertion levels over a specified period of time;

wherein the rate response curve is defined such that an exertion level corresponding to the patient's maximum exercise capacity would be mapped to a physiologically favorable maximum rate, MAR;

limiting the sensor indicated rate to a specified maximum sensor indicated rate MSR that is independent from the MAR; and,

increasing the MSR after a specified time period during which the long-term maximum exertion level is updated.

A2
3. (Amended) The method of claim 2 further comprising:

collecting daily maximum exertion levels;

periodically updating a long-term maximal exertion level of the patient to equal a maximum among the collected daily maximum exertion levels during the specified time period; and,

adjusting a slope of the rate response curve in order for the updated long-term maximal exertion level to be mapped to the MAR.

A3
5. (Amended) The method of claim 3 wherein the rate response curve is a dual-slope curve where the slope changes from a low rate response factor to a high rate response factor at a heart rate breakpoint that is computed as a percentage of the patient's rate reserve.

A4
7. (Amended) The method of claim 5 wherein the high rate response factor is adjusted to map the patient's long-term maximum exertion level to the MAR.

A5
10. (Amended) The method of claim 5 wherein a percentage of the patient's rate reserve used to compute the heart rate breakpoint is increased or decreased by the percentage increase or decrease, respectively, in the long-term maximum exertion level as a result of updating.

11. (Amended) The method of claim 1 further comprising:

collecting daily maximum exertion levels and daily maximum sensor indicated rates;
computing weekly averages of the daily maximum exertion levels and sensor indicated rates;
computing a sensor target rate as a function of the weekly average daily maximum exertion level and the patient's maximum exercise capacity as defined by the long-term maximum exertion level; and,

periodically adjusting the slope of the rate response curve in accordance with a difference between the weekly average maximum sensor indicated rate and the sensor target rate.

A6
13. (Amended) The method of claim 12 wherein the maximum exertion level is mapped to the percentage of the patient's maximum allowable heart rate in accordance with discrete thresholds relative to the patient's maximum exercise capacity in order to compute the sensor target rate.

14. (Amended) The method of claim 11 wherein the slope of the rate response curve is adjusted by a specified step amount so as to increase or decrease the responsiveness of the pacemaker in accordance with whether weekly average maximum sensor indicated rate is lesser or greater, respectively, than the sensor target rate.

15. (Amended) A system for operating a rate-adaptive pacemaker wherein measured exertion levels in a patient are mapped to a sensor indicated rate by a rate response curve, comprising:

means for automatically determining the patient's maximum exercise capacity as defined by a long-term maximum exertion level by collecting maximum measured exertion levels over a specified period of time, wherein the rate response curve is defined such that an exertion level corresponding to the patient's maximum exercise capacity would be mapped to a physiologically favorable maximum rate, MAR;

means for limiting the rate mapped by the rate response curve to a specified maximum sensor indicated rate MSR that is independent from the MAR; and,

means for increasing the MSR after a specified time period during which the long-term maximum exertion level is updated.

17. (Amended) The system of claim 15 further comprising:

means for collecting daily maximum exertion levels;

means for periodically updating a long-term maximal exertion level of the patient to equal a maximum among the collected daily maximum exertion levels during the specified time period; and,

means for adjusting a slope of the rate response curve in order for the updated long-term maximal exertion level to be mapped to the MAR.

19. (Amended) The system of claim 17 wherein the rate response curve is a dual-slope curve where the slope changes from a low rate response factor to a high rate response factor at a heart rate breakpoint that is computed as a percentage of the patient's rate reserve.

20. (Amended) The system of claim 19 wherein the rate response curve is adjusted by increasing or decreasing the low rate response factor.

Clean Version of the Amended Claims

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a8
21. (Amended) The system of claim 19 wherein the high rate response factor is adjusted to map the patient's long-term maximum exertion level to the MAR.

a9
24. (Amended) The system of claim 19 wherein a percentage of the patient's rate reserve used to compute the heart rate breakpoint is increased or decreased by the percentage increase or decrease, respectively, in the long-term maximum exertion level as a result of updating.